III. Remarks

B. Status of the Claims

Claims 1-9, 30, 41, 54, 62 and 63 have been amended without prejudice or admission.

New claims 65-73 have been added.

Support for the amended and new claims can be found in the original claims and throughout the specification. For example, support for "an amount of the antagonist released from the dosage form which has been administered intact is insufficient to produce a physiological effect of the antagonist in a human patient" can be found, e.g., on page 5, lines 8-12; on page 14, lines 5-6, and on pages 64-66 of the specification as filed. Support for the "one or more pharmaceutically acceptable excipients" can be found, e.g., on page 32, line 5. Support for "an acrylic polymer" can be found, e.g., page 29, line 36, to page 30, line 21.

Claim 60 was previously cancelled without prejudice.

Claims 1-59 and 61-73 are pending.

Applicants respectfully submit that no new matter has been added by virtue of the present amendments.

C. Claim objections

Claims 62 and 63 have been objected to under 37 C.F.R. § 1.75(c). The Examiner stated that "[t]he claims should ... recite "any one of" rather than "any of.""

Claims 62 and 63 have been amended in accordance with the Examiner's suggestion.

Withdrawal of the objection is respectfully requested.

D. Claim Rejections 35 U.S.C. § 103

1. WO 99/32120 to Palermo

Claims 1-59 and 61 and 64 have been rejected under 35 U.S.C. § 103(a) over WO 99/32120 to Palermo ("the Palermo publication").

The rejection is respectfully traversed.

In an effort to advance prosecution, independent claims 1-9, 41 and 54 have been amended without prejudice to clarify, by virtue of the "consisting of" language, that the claimed particles of the opioid antagonist do not include the opioid agonist.

The Palermo publication does not teach or suggest particles of the opioid antagonist which are free from the opioid agonist, because the Palermo publication teaches to combine an opioid agonist with an opioid antagonist such that "at least a two-step extraction process" is required to separate the opioid agonist from the opioid antagonist. The particles of the Palermo publication would therefore necessarily have both an opioid antagonist an opioid agonist.

Because opioid agonist is not part of the claimed antagonist particles and is separated from the agonist by a sequestering material, the Palermo publication does not render independent claims 1-9, 41 and 54 claims obvious.

Claims 10-40, 42-59, 61 and 64 are not rendered obvious by the Palermo publication by virtue of their dependency from claim 1-9, 41 or 54.

In response to the Examiner's statement on page 6 of the Office Action that "suitable or effective amounts can be determined by one of ordinary skill in the art through routine or manipulative experimentation to obtain optimal results," Applicants respectfully note that "obviousness cannot be proven merely by showing that a known composition could have been modified by routine experimentation or solely on the expectation of success; it must be shown

that those of ordinary skill in the art would have had some apparent reason to modify the known composition in a way that result in the claimed composition. *In Ex Parte Whallen II, Appeal No. 2007-4423, Decision of Appeal dated July 23, 2008.*

The Palermo publication does not provide such a reason, at the very least because it does not teach or suggest the desirability of the specific levels of the sequestration recited in the present claims.

In response to the Examiner's statement on page 7 of the Office Action that "the prior art does not have to teach this property (separation of agonist from antagonist), but merely that the prior art suggest using the material (hydrophobic material) for any reason," Applicants respectfully note that the Supreme Court acknowledged the importance of identifying "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *See KSR Int'l Co. V. Teleflex, Inc.*, 127 S. Ct. 1731 (2007). The Board of Patent Appeals and Interferences, in a precedential opinion In Ex Parte Whallen II, confirmed that "... obviousness cannot be proven merely by showing that the elements of a claimed device were known in a prior art; it must be shown that those of ordinary skill in the art would have had some apparent reason to combine the known elements in the fashion claimed." *In Ex Parte Whallen II, Appeal No. 2007-4423, Decision of Appeal dated July 23, 2008.*

As stated above, the Palermo publication does not provide such a reason in the present case.

Withdrawal of the rejection is respectfully requested.

2. U.S. Patent No. 6,277,384 to Kaiko et al.

Claims 1-59, 61 and 64 have been rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 6,277,384 to Kaiko et al. ("the Kaiko reference").

The rejection is respectfully traversed.

In an effort to advance prosecution and further differentiate over the Kaiko reference, independent claims 1-9, 41 and 54 have been amended without prejudice to recite that an amount of the antagonist released from the dosage form which has been administered intact is insufficient to produce a physiological effect of the antagonist in a human patient.

The Kaiko reference describes dosage forms which produce a physiological effect of the opioid antagonist in a human patient (i.e., "at least a mildly negative, "aversive" experience in physically dependent addicts"). *See, e.g., Abstract.*

The Kaiko reference does not provide a reason for one skilled in the art to formulate an oral dosage form releasing an amount of the antagonist which "is **insufficient** to produce a physiological effect of the antagonist in a human patient" upon oral administration of the intact dosage form as recited in independent claims 1-9, 41 and 54.

The Kaiko reference also does not provide a reason for one skilled in the art to formulate an oral dosage from providing the specific degrees of sequestration as recited in claims 1-7. In response to the Examiner's statement on page 11 of the Office Action that "suitable or effective amounts can be determined by one of ordinary skill in the art through routine or manipulative experimentation to obtain optimal results," Applicants respectfully reiterate that "obviousness cannot be proven merely by showing that a known composition could have been modified by routine experimentation or solely on the expectation of success; it must be shown that those of ordinary skill in the art would have had some apparent reason to modify the known composition in a way that result in the claimed composition." *In Ex Parte Whallen II, Appeal No. 2007-4423, Decision of Appeal dated July 23, 2008.*

The Kaiko reference does not provide such a reason, at the very least because the Kaiko reference is not concerned with the sequestration of the opioid antagonist as recited in independent claims 1-9, 41 and 54.

With further regard to claim 64, Applicants submit that the Kaiko reference does not suggest "an amount of the antagonist released from the dosage form which has been administered intact [that] is less than an amount bioequivalent to 0.125 mg of naltrexone" as recited in claim 64. Applicants respectfully note that "[t]the dose of naltrexone needed to elicit withdrawal symptoms in opioid dependent subjects lies between 0.25 and 1 mg," according to certain studies described in the present specification. *Specification, page 66, lines 6-7.*

For the foregoing reasons, withdrawal of the rejection is respectfully requested.

IV. Conclusion

An early and favorable action on the merits is earnestly solicited. According to currently recommended Patent Office policy the Examiner is requested to contact the undersigned by telephone in the event that a telephonic interview will advance the prosecution of this application.

Respectfully submitted,
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